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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,578	07/30/2003	Carl P. Schaffner	4892-102 US	8654

7590

11/17/2004

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,578	SCHAFFNER ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-17 is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 25-28 is/are rejected.
- 7) ☒ Claim(s) 20-24 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-29 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed October 12, 2004 has been received and entered into the application. Accordingly, the specification at page 1 and claims 1-29 have been amended.

In view of the amendments, Applicants' remarks at pages 9-12 of the amendment and the references discussed by Applicants in their amendment (copies of which have been supplied to the Examiner), the objections to the specification/claims; rejection of claims 1-29 under 35 U.S.C. § 112, first paragraph; rejection of claims 2, 4-6, 14-17, 21-24 and 29 under 35 U.S.C. § 112, second paragraph; and rejection of claims 1-14, 16-21 and 23, 24, 28 and 29 under 35 U.S.C. § 103, as set forth in the previous Office action dated May 24, 2004 are withdrawn.

It is noted that the references relied upon by Applicants to the state of the art and to rebut the Examiner's conclusion of obviousness were published subsequent to applicants' effective filing date. The references, however, are nevertheless relevant and have been properly relied upon by Applicants. "References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. Ex parte Erlich, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992) (MPEP 2124).

Claim Rejection - 35 USC § 103

Claims 18, 19 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dugar et al. (WO 94/17038), already of record as applied to claims 1-14, 16-21 and 23-29 in the previous Office action at pages 6-9 in view of Kindness et al. (U.S. Patent No. 6,534,540, newly cited by the Examiner).

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Dugar et al. disclose pharmaceutical compositions comprising the disclosed azetidinone-based cholesterol lowering agents (see the abstract and pages 3-6) and a cholesterol biosynthesis inhibitor as well as kits containing separate packaging (page 6, line 32 – page 7, line 12). At page 9, lines 16-25, cholesterol biosynthesis inhibitors for use in combination with the disclosed azetidinone-based cholesterol lowering agents are taught and include HMG CoA reductase inhibitors such as lovastatin, pravastatin, fluvastatin, simvastatin and the like.

The difference between the above and the claimed subject matter lies in that the reference fails to teach a combination of azetidinone-based cholesterol lowering agents and “at least one other anticancer agent” as required in present claims 18 and 28 and the specific article of manufacture of claim 25.

However, to the skilled artisan, the claimed subject matter would have been obvious because, as noted above, Dugar provides for cholesterol biosynthesis inhibitors for use in combination with the disclosed azetidinone-based cholesterol lowering agents and such inhibitors include HMG CoA reductase inhibitors such as lovastatin, pravastatin, fluvastatin, simvastatin and the like. The presence of these cholesterol biosynthesis inhibitors would meet the requirements for the presently claimed “at least one other anticancer agent” because HMG-CoA reductase inhibitors were known to be effective anticancer agents. See Kindness et al. at the abstract and col. 9, line 39 – col. 10, line 47.

Also, the reference specifically teaches that a kit may be used (page 7, lines 6-12) and the selection of a particular packaging arrangement, such as the claimed article of manufacture, would have been a matter well within the purview of the skilled artisan as such articles are commonly used in the pharmaceutical art to facilitate both the manufacture and distribution of

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active agents.

Applicants' Arguments

Applicants' arguments at pages 9-12 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, while applicants have persuasively argued that it would not have been obvious to administer the presently claimed azetidinone-based cholesterol lowering agents for the purpose of treating a cholesterol-associated tumor, such is not commensurate in scope with the presently claimed subject matter.

With regard to the composition, the recitation of an intended use not disclosed in the references fails to impart patentability to the claimed composition because such recitation does not provide any physical feature or otherwise material limitation to the claimed composition that is not taught or suggested by the prior art.

With regard to the claimed article of manufacture, the subject matter printed on the instruction means does not provide for a patentable distinction over a kit that would have been suggested by the prior art because such subject matter amounts to literary work and thus is not covered by patent laws, but rather copyright laws. Also, even if such were covered by patent laws, such subject matter represents no more than a statement of intended use and does not impart any physical or otherwise material limitation to the claimed kit that is either not present in the prior art or made obvious by the teachings of the prior art. It has been held that applicant is not entitled to patent a known product by simply attaching a set of instructions to that product.

See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004).

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Claim Objection

Claims 20-24 and 29 are objected to as depending from a rejected claim, but are otherwise in condition for allowance.


Allowable Subject Matter

Claims 1-17 are in condition for allowance for the reasons presented by Applicants at pages 10-12 of their amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

November 15, 2004